DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: August 5, 2014

TO: Jill Hartzler Warner, J.D.
Associate Commissioner for Special Medical Programs, FDA

THROUGH: Vince Tolino
Director, Division of Ethics and Integrity
Office of Operations

Michael F. Ortwerth, Ph.D.
Director, Advisory Committee Oversight and Management Staff
Office of Special Medical Programs

FROM: Jayne E. Peterson, J.D., B.S.Pharm.
Director, Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

Name of Advisory Committee Member: Marc Garnick, M.D.

Committees: Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

Meeting Date: September 17, 2014

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest:

Marc Garnick, M.D. owns stock in an affected firm.

The magnitude of the interest is between $25,001 – 50,000.

Description of the Particular Matter to Which the Waiver Applies:

The committees will discuss the appropriate indicated population for testosterone replacement therapy and the potential for adverse cardiovascular outcomes associated with this use.

Additional Facts:

Testosterone is a hormone essential to the development of male growth and masculine characteristics. Testosterone replacement products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure to produce testosterone due to genetics, chemotherapy, or issues with the hypothalamus and pituitary gland.

None of the FDA-approved testosterone products are approved for use in men with low testosterone levels who lack an associated medical condition. FDA-approved testosterone formulations include the topical gel, transdermal patch, buccal system (applied to upper gum or inner cheek), and injection.

FDA is currently investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. The FDA has been monitoring this risk and is reassessing the safety issue based on the recent publication of two observational studies that suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy.

The joint advisory committee meeting will discuss the appropriate patient population for whom testosterone therapy should be indicated and the potential for adverse cardiovascular effects associated with this use.

Basis for Granting the Waiver:

Dr. Garnick is the Gorman Brothers Professor of Medicine at Harvard Medical School and at the Beth Israel Deaconess Medical Center in Boston. He is board certified in internal medicine and medical oncology and is an internationally renowned expert in urologic cancer, specifically prostate cancer. Dr. Garnick has a keen understanding of urologic conditions causing testosterone deficiency because treatments he administers for prostate cancer often lead to this outcome. As a world-renowned researcher in the field of hormonal therapies for prostate cancer, Dr. Garnick is exceptionally well versed in issues related to hormones, such as testosterone. In addition, Dr. Garnick has served on several prior FDA advisory committee meetings and is familiar with the regulatory process.

On September 17, 2014, the joint committee will discuss the appropriate indicated population for testosterone replacement therapy and the potential for adverse cardiovascular outcomes associated with this use. These issues are urologic or endocrinologic in nature. Therefore, it is critical that the committee include a sufficient number urology and endocrinology experts to provide FDA with informed recommendations on the issues.

Currently, there are four individuals with urologic expertise cleared to participate in the advisory committee meeting. Agency staff strongly believes having at least five individuals with urologic expertise will ensure an opportunity to hear a spectrum of recommendations

from the urologic perspective on issues surrounding testosterone replacement therapy, and will help FDA reach an informed decision on the matters. Agency staff has attempted to obtain others with urologic expertise but has not been successful, despite contacting an additional six individuals with urologic expertise. Of the six additional experts invited, four have scheduling conflicts and two self-recused because of conflicts of interest.

Further, in the interest of public health, it is critical for the agency to have Dr. Garnick participate and give his expert opinion on the matters coming before the committees. As mentioned above, the FDA is currently investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. These are controversial and complex topics with considerable public health implications, and the outcome of this advisory committee meeting could lead to significant changes to the drug labels for the entire testosterone class. Therefore, it is critical that the committees include a sufficient number of individuals with appropriate expertise to provide FDA with informed recommendations.

Given Dr. Garnick's excellent credentials, and difficulties in securing others with urologic expertise for this advisory committee meeting, agency staff strongly recommend that Dr. Garnick be allowed to participate in the meeting discussion on the appropriate patient population for whom testosterone therapy should be indicated, and the potential for adverse cardiovascular effects associated with this use. Agency staff believes that it would be extremely difficult to replace Dr. Garnick, and excluding him from participation will have a significantly negative effect on the committee deliberations.

Accordingly, I recommend that you grant a waiver for Marc Garnick, M.D., a temporary member of the joint BRUDAC/DSaRM, from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

___x____ The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

_____ Non-voting

_____ Other (specify):

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_____

_____ Denied – The individual may not participate.

_____/S/_____ __08/25/2014____
Jill Hartzler Warner, J.D. Date
Associate Commissioner for Special
Medical Programs